IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Michel H. Malek
Title:	SPINE STABILIZATION SYSTEMS
Appl. No.:	10/722,119
Filing Date:	11/25/2003
Examiner:	David C. Comstock
Art Unit:	3733
Confirmation Number:	4839

PRE-APPEAL BRIEF REQUEST FOR REVIEW

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Commissioner for Patents
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Sir:

In accordance with the **Pre-Appeal Brief Conference Pilot Program**, announced July 11, 2005, this Pre-Appeal Brief Request is being filed together with a Notice of Appeal. This communication is responsive to the Advisory Action, dated June 26, 2008, concerning the above-referenced patent application, and the Final Office Action, mailed on April 2, 2008. Applicant also encloses a petition for a two-month extension of time, and, as such, Applicant believes this pre-appeal brief to be timely filed.

REMARKS

Applicant respectfully requests that the Panel reconsider the present application in view of the reasons that follow. Claims 1-3, 6, 7, 9-22 and 26 are pending in this application.

Rejection of Claims 1, 2, 4-12, 16-25, and 43 Under 35 U.S.C. § 102(b)

On page 2 of the Office Action, Claims 1, 2, 4-12, 16-25, and 43 were rejected under 35 U.S.C. § 102(b) as anticipate by US Patent No. 6,241,730, issued to Alby. Because Alby does not teach each and every element of the pending claims, Alby cannot anticipate the claims. The rejection is clearly improper and in error, and this case is properly before the Pre-Appeal Brief Panel for reconsideration of the rejection.

Claim 1 of the presently claimed invention recites:

> A spinal stabilization system comprising:
> (a) **a stabilizing element** comprising a first segment and a second segment, the first and second segments connected by a pivoting joint;
> (b) a first connector adapted to connect the stabilizing element to a first vertebra in a spinal column;
> (c) a second connector adapted to connect the stabilizing element to a second vertebra in the spinal column; **and**
> (d) **a disc prosthesis or a disc nucleus replacement** adapted to be disposed ***between two adjacent vertebrae*** in the spinal column.

Emphasis added. Hence, a system is presented having a stabilizing element AND a disc prosthesis or disc nucleus replacement. Furthermore, the disc prosthesis or disc nucleus replacement is adapted to be disposed *between* two adjacent vertebrae. The claim clearly states each of these elements, and all elements must be given weight in determining the patentability of the claim in view of Alby.

A disc prosthesis is fully described by the present specification in paragraph 6:

> ...disc prostheses may be inserted in place of a natural vertebral disc in order to simulate at least some of the natural intervertebral movement and to restore proper disc height. Ideally, a disc prosthesis will operate in conjunction with the facet joints to restore the full range of motion of the spine.

This is not mere exemplification, but is a description of a disc prosthesis, where it is "inserted in place of a natural vertebral disc." Furthermore, a disc nucleus replacement is exactly as described, in that it replaces a disc nucleus. Such items are more fully described with reference to at least figure 7 of the specification as originally filed. In figure 7, a disc prosthesis 724, is shown sandwiched between adjacent vertebrae. To "replace" a disc nucleus requires that the item be placed where the disc nucleus would naturally reside. In fact, claim 1 requires that the disc prosthesis or disc nucleus replacement be adapted to be disposed between two adjacent vertebrae in a spinal column. To use anything outside of the alignment within the spinal column would not be a disc prosthesis or disc nucleus *replacement*, within the meaning of the claim.

In the 35 U.S.C. § 102 rejection of the Final Office Action, the Examiner has failed to point to any feature of Alby that is a disc prosthesis or disc nucleus replacement. Instead, in the Advisory Action, and again in a brief telephone discussion on July 29, 2008, the Examiner alleged that a disc nucleus replacement external to the disc space meets the element of a disc nucleus replacement. The Examiner has not accounted for each and every element of the claim, particularly the requirement that the disc prosthesis or disc nucleus replacement is adapted to be disposed *between two adjacent vertebrae* in the spinal column.

The Examiner alleged that elastically deformable members (i.e. 7A in FIG. 1) can be construed to be a disc nucleus replacement. In the advisory action, the Examiner stated: "that a system may be external to a disc space is irrelevant to the question of whether it acts in some way as a substitute for a damaged disc." Applicant does not need to comment on the veracity of this allegation, for it completely ignores the requirement in the claim that the disc prosthesis or disc nucleus replacement be adapted to be disposed between two adjacent vertebrae.

The claims clearly do not read on the device of Alby, for Alby fails to at least teach the item of a "disc prosthesis or a disc nucleus replacement be adapted to be disposed between two adjacent vertebrae." As such, the requirements for a rejection based upon anticipation have not been met and Applicant requests that the Panel find the same.

Rejection of Claims 13 and 14 Under 35 U.S.C. § 103(a)

Claims 13 and 14 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Alby in view of U.S. Patent No. 6,217,578, issued to Crozet *et al.* Alby fails to teach each and every element of the claims as described above. Therefore, to establish a case of obviousness, Crozet must be relied upon to fill in at least the missing element of a "disc prosthesis or a disc nucleus replacement be adapted to be disposed between tow adjacent vertebrae." Crozet fails as well, and thus this rejection is clearly improper and in error as well.

Crozet is directed to a vertebral osteosynthesis device that can be used to brace a spine or to strengthen or brace a deviated spine. Col. 1, lines 5-11. To accomplish this, the device provided is a cross connector device having a low profile that allows for substantial degree of freedom between the hooks of the device. Col. 2, lines 15-18. The cross connector device is for coupling dual rods of an orthopaedic apparatus together to provide enhanced stability thereto. Col. 7, lines 29-32. There simply is no teaching of a device with at least the element of "a disc prosthesis or a disc nucleus replacement."

Without establishing each and every element of the claims as pending, a case of obviousness has likewise not been established based upon Alby and Crozet. MPEP § 2143(A).

Claim 15 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Alby in view of U.S. Patent No. 6,214,012, issued to Karpman *et al.* Alby fails to teach each and every element of the claims as described above. Therefore, to establish a case of obviousness, Karpman must be relied upon to fill in at least the missing element of a "disc prosthesis or a disc nucleus replacement be adapted to be disposed between tow adjacent vertebrae." Karpman fails as well, and thus this rejection is clearly improper and in error as well.

Karpman is directed to a bone screw which is configured for delivery of an injectable material into a bone. Col. 1, lines 6-9. Applicant submits that while a bone screw is taught for the delivery of a material to a diseased site, there is no teaching or suggestion in Karpman of at least the element of "a disc prosthesis or a disc nucleus replacement." As such, each and every element of the claims as pending have not been shown and hence a case of obviousness has not been established based upon Alby and Karpman.

Summary

For both rejections under anticipation and obviousness, each and every element of a pending claim must be shown either expressly or inherently. For anticipation, this requires each and every element in a single prior art reference, and for obviousness, a single or multiple prior art references may be used. In the present case, there is at least one element that is missing.

In rejecting the claims, the Examiner alleges that a deformable member can *act* as a disc replacement, and that it does not matter if the disc replacement is external to the disc space. However, this clearly ignores at least the element of the claim that requires the disc replacement to be adapted to be disposed between two adjacent vertebrae of a spinal column. The devices of Alby, Crozet, and Karpman, do not show at least this feature. The rejections are clearly improper and Applicant respectfully requests the Panel to correct this error.

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance.

Respectfully submitted,

Date August 26, 2008

By _____

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